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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

ROMEO, DAVID S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 01/02/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/574,819

Applicant(s)

LUYTEN ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-40 is/are pending in the application.
- 4a) Of the above claim(s) 33-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed October 15, 2002 (Paper No. 10) has been entered. Claims 27-40 are pending.

5 Newly submitted claim 40 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 40 is directed to a CDMP-1 amino acid sequence, classified in class 530, subclass 350. Claims 27-39 are directed to a CDMP-1 polynucleotide, classified in class 536, subclass 23.5. The inventions are distinct, each form the other because of the following reasons: The polynucleotides of the invention originally
10 claimed (claims 27-39) are related to the polypeptide of claim 40 by virtue of encoding same. The polynucleotide has utility for the recombinant production of the polypeptide in a host cell. Although the polynucleotide and polypeptide are related since the polynucleotide encodes the specifically claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the polypeptide product can be made by another and
15 materially different process, such as by synthetic polypeptide synthesis or purification from the natural source. Further, the polynucleotide may be used for processes other than the production of the polypeptide, such as a nucleic acid hybridization assay. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Because
20 these inventions are distinct for the reasons given above and the searches required are not coextensive, restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art

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because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution
5 on the merits. Accordingly, claim 40 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Newly submitted claims 33-39 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly submitted claims 33-39
10 are directed to a biological material encoding SEQ ID NO: 17. The invention originally claimed is to a DNA molecule not encoding SEQ ID NO: 17. In addition, newly submitted claims 33-39 and the invention originally claimed require separate searches.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution
15 on the merits. Accordingly, claims 33-39 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 27-32 are being examined. Any objection and/or rejection of record that is not maintained and/or repeated in this Office action is withdrawn. The text of those sections of Title
20 35, U.S. Code not included in this action can be found in a prior Office action. Citations by the examiner are in an alphanumeric format, such as "(a1)", wherein the "a" refers to the reference

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cited on the Notice of References Cited, PTO-892, and the "1" refers to the Paper No. to which the Notice of References Cited, PTO-892, is attached.

Maintained Formal Matters, Objections, and/or Rejections:

5 ***Claim Rejections - 35 USC § 112***

Claims 27-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10 Applicants argue:

that reduction to drawings or structural chemical formulas are sufficiently detailed to show that applicant was in possession of the claimed genus;

that CDMP family members from several species shared a common, highly conserved motif of 31 amino acid residues, that this structural conservation therefore represented a functional domain that is characteristic of CDMP family of proteins, and that this motif is critical to the biological activity of CDMPs;

that SEQ ID NO: 15 would be appreciated by one of ordinary skill in the art as indicative of a functional domain;

that SEQ ID NO: 15 is a chemical structure that represents a functional domain;

20 that other distinguishing structural attributes shared by members of the genus are unimportant and need not be indicated;

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that an additional definition by function is indicated by the requirement that the protein be a member of the TGF- β family;

that in the present case the definition is not by function alone but is by chemical structure and that SEQ ID NO: 15 demonstrates that applicant had possession of the claimed genus; and,

5 that Applicants need not rely on other identifying characteristics.

Applicant's arguments have been fully considered but they are not persuasive. The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. In the present case

10 there are no functional limitations to the polypeptide encoded by the claimed nucleic acid molecule or to the polypeptide produced by the claimed process. The structure set forth in the claims, SEQ ID NO: 15, is only a 31 amino acid portion of what appears to be an at least 120 amino acid mature, active polypeptide. The present specification does not describe a specific function that is characteristic of this 31 amino acid domain. The specification does not attribute
15 a functional limitation to SEQ ID NO: 15 that is characteristic of the full length, mature, or active polypeptides comprising SEQ ID NO: 15. A member of the TGF- β family is substantially broader than a description of a CDMP because the TGF- β superfamily comprises a broad genus of structurally related but functionally distinct molecules. Accordingly, a description of SEQ ID NO: 15 is not a description of a full length, mature, or active protein of the TGF- β family
20 comprising SEQ ID NO: 15. Rasmussen can be distinguished from the present case because unlike Rasmussen wherein the claims recited a functional limitation, the present claims do not recite a functional limitation.

New formal matters, objections, and/or rejections:

Claim Rejections - 35 USC § 112

Claims 27-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject
5 matter which was not described in the specification in such a way as to reasonably convey to one
skilled in the relevant art that the inventor(s), at the time the application was filed, had
possession of the claimed invention. Support for the limitation wherein the sequence is not SEQ
ID NO: 17 cannot be found in the disclosure as originally filed and its introduction raises the
issue of new matter. Applicants argue that the support for this limitation can be found
10 throughout the specification and in Figure 4. Applicants arguments have been fully considered
but they are not persuasive. Support for this limitation cannot be found either in the specification
or in Figure 4. Further, Figure 4 specifically identifies SEQ ID NO: 17 as a portion of human
CDMP-1, and SEQ ID NO: 17 is used to derive the consensus sequence SEQ ID NO: 15
(specification at paragraph bridging pages 11-12). Moreover, the original disclosure does not
15 explicitly disclaim SEQ ID NO: 17 and makes it reasonably clear that Applicants did not intend
to exclude SEQ ID NO: 17.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the
20 basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

This rejection is based upon an effective filing date of December 7, 1993 for Celeste.

5 Claims 27-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Celeste (a11).

Celeste teaches a protein of the TGF- β family wherein said protein comprises the sequence

WIIAPLDYEAYHCEGLCDFPLRSHLEPTNHA (amino acids +20 to +50 of SEQ ID NO: 2), which is

encompassed by SEQ ID NO: 15 of the present claims with the proviso that the sequence is not

SEQ ID NO: 17, an isolated DNA molecule encoding the protein (column 2, lines 5-26),

10 expression vectors comprising the DNA molecule (column 2, lines 27-32; column 9, lines 15-

42), eukaryotic and mammalian host cells transformed with the vector (column 8, line 34,

through column 9, line 14), and a process for the production of the protein comprising culturing

the host cells in a culture media and isolating the protein (column 8, lines 23-34).

15 *Conclusion*

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

20 Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5

Recent Statutory Changes to 35 U.S.C. § 102(e)

On November 2, 2002, President Bush signed the 21st Century Department of Justice Appropriations Authorization Act (H.R. 2215) (Pub. L. 107-273, 116 Stat. 1758 (2002)), which
10 further amended 35 U.S.C. § 102(e), as revised by the American Inventors Protection Act of 1999 (AIPA) (Pub. L. 106-113, 113 Stat. 1501 (1999)). The revised provisions in 35 U.S.C. § 102(e) are completely retroactive and effective immediately for all applications being examined or patents being reexamined. Until all of the Office's automated systems are updated to reflect the revised statute, citation to the revised statute in Office actions is provided by this
15 attachment. This attachment also substitutes for any citation of the text of 35 U.S.C. § 102(e), if made, in the attached Office action.

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 in view of the AIPA and H.R. 2215 that forms the basis for the rejections under this section made in the
20 attached Office action:

A person shall be entitled to a patent unless –

25 **(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if**
30 **the international application designated the United States and was published under Article 21(2) of such treaty in the English language.**

35 U.S.C. § 102(e), as revised by the AIPA and H.R. 2215, applies to all qualifying references, except when the reference is a U.S. patent resulting directly or indirectly from an international
35 application filed before November 29, 2000. For such patents, the prior art date is determined under 35 U.S.C. § 102(e) as it existed prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

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The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 prior to the amendment by the AIPA that forms the basis for the rejections under this section made in the attached Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

For more information on revised 35 U.S.C. § 102(e) visit the USPTO website at www.uspto.gov or call the Office of Patent Legal Administration at (703) 305-1622.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

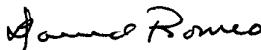
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647